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10/789,653	02/28/2004	Paul A. Lovoi	687P	9189

7590 06/13/2005  
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EXAMINER

THOMAS, COURTNEY D

ART UNIT PAPER NUMBER

2882

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

10/789,653

Applicant(s)

LOVOI ET AL.

Examiner

Courtney Thomas

Art Unit

2882

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-22 and 41-44 is/are allowed.
- 6) ☒ Claim(s) 23-26 and 30-40 is/are rejected.
- 7) ☒ Claim(s) 27-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 07/06/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The drawings were received on 02/28/04. These drawings are acceptable for examination purposes only.

### *Claim Objections*

1. Claims 1-44 are objected to because of the following informalities:
2. Claim 1 recites: “ A cooling system ...” Dependent claims (2-22) recite an apparatus. Examiner suggests dependent claims be re-written to coincide with the claimed subject matter of independent claim 1 - (see also corresponding dependent claims of independent claim 23).
3. Claim 1, line 15 recites: “...delivery of the coolant liquid toward ***the proximal direction*** of (emphasis added) ...” Examiner notes there is no antecedent basis for the use of this term (see also claim 23, lines 23-24).
4. Claim 1, line 19 recites: “... so as efficiently to cool the anode ...” Examiner suggests the phrase be re-written for clarity as follows: “... so as to efficiently to cool the anode ...”
5. Claim 5, line 2 recites: “...the path...” Examiner notes there is no antecedent basis for the use of this term
6. Claim 18A does not appear to be numerated in accordance with MPEP 608.01(i) - see 37 CFR 1.75 (f). Accordingly, subsequent claims 19-44 are similarly objected to and should be re-numbered (as well as any corresponding dependencies) in accordance with a change to claim 18A.
7. Claim 18A, lines 5-7 recite: “... having a flexible outer wall such that a vacuum ***can be*** (emphasis added) applied to the inflow lumen while the catheter is implanted, to shrink the

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diameter of the catheter, then the catheter *can be* (emphasis added) re-expanded when coolant liquid is pumped through the catheter.” Examiner notes that the language describing the functional properties of a flexible catheter wall and catheter diameter appear to be optional. It is unclear whether the functionality of the aforementioned components is to be considered as inclusive within the claim. Examiner suggests the claim be re-written to obviate the optional language as follows: “... having a flexible outer wall configured to sustain a vacuum ~~such that a vacuum can be~~ applied to the inflow lumen while the catheter is implanted, to shrink the diameter of the catheter; ~~then the catheter can be~~ configured to re-expanded when coolant liquid is pumped through the catheter.” (see also claim 32, line 7; claim 35, lines 3 and 4).

8. Claim 27, line 24 recites: “... the coolant delivery head.” Examiner notes there is no antecedent basis for the use of this term.

9. Claim 41 line 13 recites: “... the coolant liquid...” Examiner notes there is no antecedent basis for this term. Examiner suggests the term be re-written as: “... a coolant liquid...”

10. Claim 44 line 21 recites: “...the anode...” Examiner suggests the term be re-written as: “...the anode end...” to maintain consistency throughout the claim.

11. The claims have not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the claims.

12. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 23-26, 30-32, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (U.S. Patent Re. 34,421) in view of Chornenky et al. U.S. Patent Publication (US 2004/0218724).

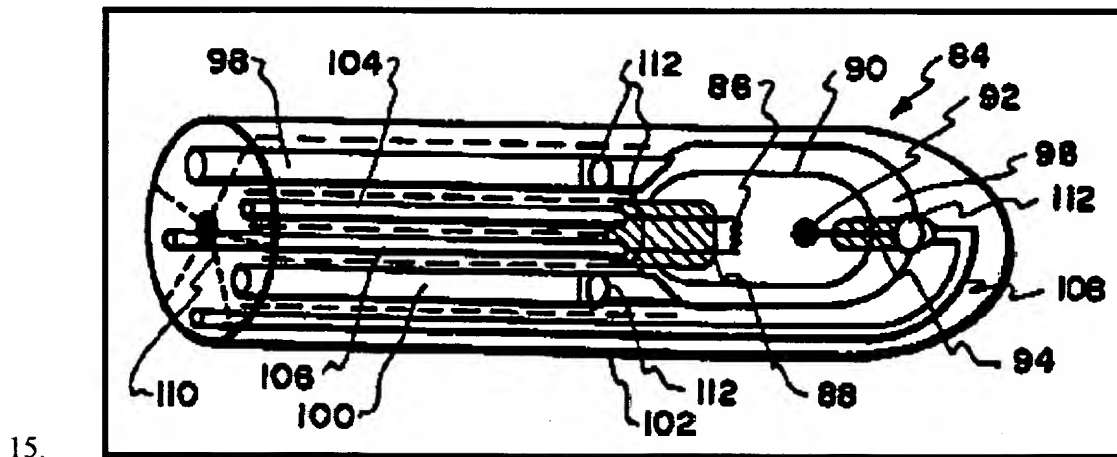
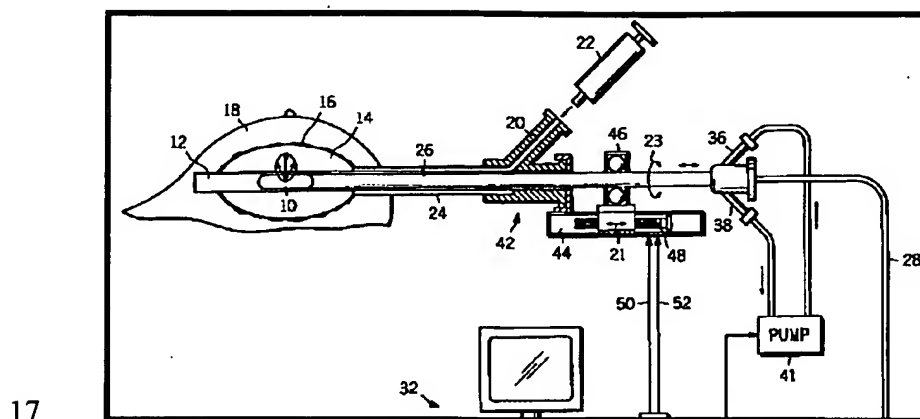


Figure 10 – Miniature X-ray Tube – U.S. Patent (RE 34,421) to Parker et al.

16. As per claim 23, Parker et al. disclose a cooling system comprising a catheter having multiple lumens (98, 100) for carrying a liquid coolant (column 10, lines 22-26); an X-ray tube (84) contained in a distal end of the catheter; the X-ray tube having an anode end (92) near the distal end of the catheter; the liquid coolant flowing over the anode end of the X-ray tube - see Fig. 10 above; column 10, lines 22-35). Parker et al. do not explicitly disclose at least two lumens including an outer lumen serving as an inflow lumen for coolant liquid and an inner lumen serving as an outflow lumen.



**Figure 1 - Miniature X-ray emitter- U.S. Patent Publication (US 2004/0218724) to Chornenky et al.**

18. Chornenky et al. disclose a cooling system comprising an inflow lumen (36) and an outflow lumen (38); lumen (36) as illustrated above, serves as a means for directing coolant liquid to a distal end of an X-ray tube (10), while lumen (38) serves as a return lumen, drawing the coolant liquid and heat away from the distal end of the X-ray tube (10)- para. [0020].

19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Parker et al. such that it incorporated the system of Chornenky et al. One would have been motivated to make such a modification for the purpose of providing means for delivering coolant liquid to at distal end of an X-ray tube and means for removing the liquid from the distal end, thereby removing heat from the X-ray tube as taught by Chornenky et al. (para. [0020]).

20. **As per claims 24 and 38**, Parker et al. as modified above, disclose a system including a coolant reservoir tank and pump (41) for receiving coolant liquid returning from the X-ray tube and delivering coolant liquid to the inflow lumen (Chornenky et al. – para. [0020]).

21. **As per claims 25 and 26**, Parker et al. as modified above, do not explicitly disclose a system wherein the coolant liquid includes a surfactant to reduce surface tension or is degassed.

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22. It would have been obvious to one having ordinary skill in the art to further modify the system of Parker et al. such that it incorporated a coolant liquid with a surfactant and/or wherein the coolant liquid is degassed. One would have been motivated to make such modifications for the purpose of enhancing viscosity of the coolant liquid, thereby improving heat transfer characteristics of the coolant fluid, as recognized by artisans in the X-ray tube art.

23. **As per claims 30, 31, 34 and 37**, Parker et al. as modified above, do not explicitly disclose a system wherein the coolant liquid flows into the catheter at a temperature in the range of about 0 to 37 degrees Celsius; the at the coolant flows into and out of the catheter at a rate of less than 150cc per minute or the system including temperature and pressure monitors to monitor coolant liquid temperature and flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the system of Parker et al. such that the aforementioned limitations were incorporated. One would have been motivated to make such a modification for the purpose of ensuring that the coolant liquid temperature and the corresponding X-ray tube operating temperature possessed a considerable differential such that thermal flow is easily facilitated and heat is removed from the X-ray tube. Additionally, one would be motivated to regulate coolant flow such that new coolant liquid volume is constantly in contact with the tube, thereby efficiently removing heat from the source, as recognized by artisans in the X-ray tube art.

24. **As per claims 32**, Parker et al. as modified above, disclose a system wherein the catheter includes a flexible exterior wall portion in an area of the X-ray tube (para [0020]).

25. **As per claims 35-36 and 39-40**, Parker et al. as modified above, disclose a system wherein the inflow lumen is in an outer portion of the catheter, the inflow lumen having a

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flexible outer wall formed of an insulator (Parker Fig. 2, not shown above); and further including an inflatable applicator balloon (14) near the distal end of the catheter.

26. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (U.S. Patent Re. 34,421) and Chornenky et al. U.S. Patent Publication (US 2004/0218724), in view of Forman et al. (U.S. Patent 6,390,967).

27. As per claim 33, Parker et al. modified in view of Chornenky et al. do not explicitly disclose a system wherein the X-ray tube is translatable axially within the catheter.

28. Forman et al. disclose an X-ray tube translatable axially within a catheter (column 6, lines 58-63).

29. It would have been obvious to further modify the apparatus of Parker et al. such that it incorporated an X-ray tube translatable axially within the catheter. One would have been motivated to make such a modification for the purpose of delivering uniform radiation along an axis of a patient, as suggested by Forman et al. (column 6, lines 58-63).

***Allowable Subject Matter***

30. Claims 1-18A, 19-22 and 41-44 are allowed.

31. The following is a statement of reasons for the indication of allowable subject matter:

32. As per claim 1 and dependent claims 2-18 and 18A-22, the examiner found no reference in the prior art that disclosed or made obvious a cooling system for a miniature X-ray tube, comprising: a catheter including a coolant delivery head distal relative an anode, for receiving coolant from at least one inflow lumen of the catheter and for delivering a distributed flow of coolant liquid over the anode end of the X-ray tube; the delivery head having a coolant entry end fluidly connected to the inflow lumen and having a wall with a series of orifices for



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delivery of the coolant liquid toward a proximal direction of the catheter, toward and over the anode end; the orifices being spaced apart and distributed in position so as to spread the coolant liquid over substantially the entire area of the anode end so as to efficiently cool the anode, as recited in independent claim 1.

33. **As per claim 41 and dependent claims 42 and 43**, the examiner found no reference in the prior art that disclosed or made obvious a cooling system for a miniature X-ray tube comprising: a catheter including a flow channel connecting at least one lumen to an interior of an applicator balloon and fluid communication means in the catheter for providing fluid communication between liquid in the applicator balloon when inflated and the anode end of the X-ray tube, for static cooling of the X-ray tube by a coolant liquid which also inflates the applicator balloon as recited in independent claim 41.

34. **As per claim 44**, the examiner found no reference in the prior art that disclosed or made obvious a cooling system for a miniature X-ray tube comprising: an inflatable balloon near a distal end of a catheter including a liquid flow channel comprising one of multiple lumens and carrying inflowing coolant liquid, the flow channel communicating with the applicator balloon to inflate the applicator balloon with coolant fluid; the liquid flow channel continuing from the applicator balloon to flow liquid over the anode end of the X-ray tube and including an outflow channel comprising another one of the multiple lumens, positioned to carry liquid that has flowed over the anode end in a return direction out of the human body as recited in independent claim 44.

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35. Claims 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

36. **As per claim 27 and dependent claims 28 and 29**, the examiner found no reference in the prior art that disclosed or made obvious a system; wherein the catheter comprises two concentric extrusions, including an outer extrusion and an inner extrusion, the inner extrusion having radially inwardly extending ridges on its interior, positioned and sized to engage an exterior surface of the miniature X-ray tube, and one of the inner and outer extrusions having, on its surface facing toward the other, stand-of ridges that engage the surface of the other extrusion, forming between the inner and outer extrusions at least one coolant flow channel, serving as the inflow lumen of the catheter for inflow of coolant liquid toward a coolant delivery head.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney Thomas whose telephone number is (571) 272-2496. The examiner can normally be reached on M - F (9 am - 5 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Courtney Thomas". The signature is written in a cursive, flowing style.

Courtney Thomas  
Examiner  
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